PSJ4 SOL Opp Exh 38

Message

From: Howenstein, Kim [/O=CAH/OU=CARDINAL HEALTH/CN=RECIPIENTS/CN=KIM.HOWENSTEIN]
Sent: 4/28/2014 5:17:19 PM
To: Anna-Soisson, Kimberly [/O=CAH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=Kimberly.anna-soisson]
Subject: FW: assitance
Attachments: DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS.docx; QRA SOM Customer Analytics.docx

This is should be a good start.
The first attachment is an SOP
The second attachment is working guidelines.

From: Mayeski, Ullrich
Sent: Monday, April 28, 2014 12:18 PM
To: Howenstein, Kim; Anna-Soisson, Kimberly
Subject: assitance

Happy Monday:

I need some help. I am meeting with all of the compliance officers next week here in Dublin. There are several topics that I have to address. One of them is how the compliance officers would facilitate an overview conversation about the SOM program during a DEA cyclic inspection. Can the two of you create a 6-7 slide presentation that addresses an overview of our program. This is something the compliance officers would share with DEA on-site and walk through with them during the inspection? The COs have a basic understanding about SOM, but this should be fairly hi level addressing basic components, particularly what happens when a threshold hits and cutting/reporting.

Oh and I need it by Thursday. You are the best!!

CardinalHealth

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CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide guidance to Cardinal Health employees in the Quality and Regulatory Affairs (QRA) department on responding, detecting and reporting suspicious orders, and processing, documenting and making judgments about threshold events, including making decisions about adjusting thresholds, releasing orders, or cutting orders.

It is also the purpose of this SOP to comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, and extra-regulatory guidance to which Drug Enforcement Administration (DEA) holds distributors responsible.

2.0 SCOPE

This SOP applies when an order is triggered by the Cardinal Health Anti-Diversion Centralization (or equivalent) system for evaluation so as to meet the purpose of the SOP mentioned in §1.0 above.

3.0 REFERENCES / RELATED DOCUMENTS

PDQRA-CAD-C008	On-Site QRA and Surveillance Investigations
fda.gov/regulatoryinformation/legislation/ucm148726.htm	Controlled Substances Act
deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm	21 CFR 1301.74(b)

4.0 RESPONSIBILITIES

The responsibilities of QRA includes

a. Evaluating threshold events
b. Identifying suspicious orders
c. Reporting suspicious orders to DEA
d. Performing a review of suspicious orders
e. Making decisions regarding threshold adjustments
f. Cutting suspicious orders when appropriate
g. Releasing portions of orders when appropriate

5.0 DEFINITIONS

Anti-Diversion Centralization (ADC) System	Case management system used to facilitate the evaluation and assessment of threshold events, which are orders for controlled substance products held by the Suspicious Order Monitoring (SOM) electronic monitoring program. The case management system also allows members of Quality and Regulatory Affairs to reference customer specific information, as well as make adjustments to threshold limits and restrict customers from purchasing controlled substances.
Threshold	The maximum quantity of a regulated drug permitted to be automatically shipped to a specific licensed customer.
Threshold Event	An order for a regulated drug which exceeds the threshold set for a specific licensed customer.

6.0 PROCEDURE

6.1 Initial Review

6.1.1

The following orders are held or cut pending review by QRA under this procedure

a. Orders of interest referred to by a Forward Distribution Center
b. Orders that exceed a threshold set for the customer for the drug family
c. Orders that exceed any other criteria established by QRA

6.1.2 In addition, under this SOP, QRA can review other orders that may come to the attention of QRA based on any other criteria.

6.1.3 Under this procedure, QRA must first review every held order under §6.1.1 to determine whether the order is suspicious as that term is used in 21 CFR. 1301.74(b). Per the regulation, orders are deemed suspicious if they meet one (1) or more of three (3) criteria:

a. Order is of unusual size
b. Order is of unusual frequency
c. Order deviates substantially from a normal pattern for the customer

6.1.4 Orders that meet one or more of the criteria in §6.1.3 must be reported to the DEA as suspicious.

6.1.5 **Orders of unusual size** are significantly larger than the orders normally placed by the customer or by customers that have a size and type of business that is similar to the ordering customer's business.

6.1.5.1 Orders of unusual size can be as a result of:

a. Unintentional order entry errors (including duplicate order entries)
b. Intentional orders placed by the customer

QRA personnel must use available information and prior experience to determine if the order is an unintentional order entry error or intentional order placed by the customer.

6.1.5.2 Unintentional order entry errors (including duplicate order entries) must be cut and reported to the DEA as suspicious, with no changes to customer threshold.

6.1.5.3 QRA personnel must use available information and prior experience to determine if the order of unusual size is intentional. If QRA personnel determines the order to be intentional and of unusual size then the order is cut and reported to the DEA as suspicious.

6.1.6 **Orders of unusual frequency** are orders that occur significantly more frequently than the orders normally placed by the ordering customer or by customers that have a size and type of business that is similar to the ordering customer's business.

6.1.6.1 QRA personnel can use available information on order history and prior experience on other customers that have a size and type of business similar to the ordering customer to determine if the order is of unusual frequency.

6.1.6.2 If QRA personnel determines the order to be of unusual frequency then the order is cut and reported to the DEA as suspicious.

6.1.7 **Orders that deviate substantially from the normal ordering pattern** are orders that reflect a significant deviation from the customer's normal orders or that deviate substantially from the ordering patterns of customers that have a size and type of business that is similar to the ordering customer's business.

6.1.7.1 Substantial deviations in ordering patterns include, but are not limited to,

a. Orders for an unusually high percentage of controlled substances compared to non-controlled substances.
b. Orders for an unusually high percentage of a particular strength of drug that is known or suspected of being widely diverted.
c. Orders that are cumulatively larger than expected for the customer even though individual orders may not be unusually large.

d. Other deviations based on QRA personnel's experience.

6.1.7.2 QRA personnel can use available information and prior experience on other customers that have a size and type of business similar to the ordering customer to determine if the order deviates substantially from the normal ordering pattern.

6.1.7.3 If the QRA personnel determines that the order deviates from normal ordering pattern then the order is cut and reported to the DEA as suspicious.

6.2 Review of Suspicious Orders

6.2.1 A held order that warrants an assessment is reviewed as described in written procedures to determine whether a threshold adjustment to the particular drug family is warranted.

6.2.1.1 When the QRA personnel determines that a threshold adjustment is warranted because the personnel has found that the drugs are unlikely to be diverted, the personnel must ensure that the reasons for adjusting the threshold and relevant information considered have been recorded prior to adjusting the threshold.

6.2.1.2 When the QRA personnel is unable to determine with information available that the order is not likely to be diverted, the current order and subsequent orders in the same drug family, above threshold, are cut, when appropriate, and reviewed on an individual basis to determine if a site visit is warranted.

6.2.2 **Selection of a suitable type of site visit** (refer to PDQRA-CAD-C008 for conducting site visits).

6.2.2.1 The site visit type is determined by QRA personnel following written procedures.

6.2.3 **Decision based on findings of the site visit**

6.2.3.1 If the decision is to suspend the customer, the current order and subsequent orders in the same drug family are cancelled and the threshold is set at one (1).

6.2.3.2 If the decision is to retain the customer, the QRA personnel must:

a. Continue to monitor the customer; and
b. Determine if the customer's threshold levels should be considered for adjustment and make adjustments if necessary following written procedures.

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 Not applicable.

7.2 Documentation Retention

7.2.1 Not applicable.

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

Approvals					
Approvals on file in the Pharmaceutical Distribution Corporate Document Center Approvers: Todd Cameron				Owner: Danielle Holbrook PDCDC Coordinator: Jason Paul Snouffer	
Change History					
DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
3310	18 Jul 2013	Modify	Yes	Corporate	PDQRA - Analytics and SOM Compliance PDQRA - Pharmacy Assessment
Other (specify)					
N/A					
Change Description and Justification					
Review process for held orders has been enhanced and updated.; Document Approver was updated from Nicholas Rausch to Todd Cameron.					

QRA SOM Customer Analytics
General Work Instructions

Scope

These general guidelines are limited to Retail Independent and Retail Chain customers ordering controlled substances through the core pharmaceutical distribution business[1], as well as the thirteen drug families[2] designated as having a high risk for abuse and diversion. These guidelines apply to all individuals who have the ability and/or direct responsibility for assessing and adjusting customer threshold limits for the aforementioned customers and drug families.

Effective Date

January 15, 2013

Statement

Cardinal Health's QRA department will have a standardized method to assess and adjust threshold limits utilized within the electronic monitoring system of the Suspicious Order Monitoring (SOM) program.

For purposes of these guidelines, the assessment and adjustment process is outlined from initiation to conclusion. The initiation of an assessment could result from an early dialogue notice, held order, or proactive communication from the customer or sales department. The assessment could conclude with no change of a threshold limit, an increase or decrease of a threshold limit, resolution of a held order, and/or the report of a suspicious order to DEA.

The following outlines the sequence of steps and corresponding decisions that should generally occur for each type of assessment.

1. **Determine customer's class of trade:** The guidelines only apply to Retail Independent and Retail Chain customers. If the customer's class of trade is Retail Independent or Retail Chain, proceed to step 2.

    a. Class of trade can be found within ADC, indicated as Business Activity, on the Account Info tab of the Customer Details dashboard.
    b. Customers within other classes of trade are to be managed by the Director of Pharmacy or designated individual on that team.

2. **Evaluate type of assessment:** Three distinct mechanisms may initiate the need to review a customer's threshold limit. These mechanisms include:

    a. Held order: order held by the electronic monitoring system, occurring when a customer's accrual exceeds the threshold limit. All orders held by the electronic monitoring program will appear in ADC.
    b. Early dialogue: notification that occurs when a customer's accrual approaches the threshold limit. All early dialogue notifications will appear in ADC (and a case may be created if step 3 concludes that an assessment is warranted).
    c. Proactive review: occurring when a sales representative or other party proactively communicates to QRA the potential need for review. The communication could occur via email or via a phone conversation.

[1] Core pharmaceutical distribution business includes customers serviced by the 20 forward distribution centers.
[2] See Appendix 1 for the List of 13 Drug Families.

3. **Determine if assessment is warranted:** An evaluation of the set of circumstances specific to each customer is needed in order to determine if an assessment of the threshold limit is warranted. The set of circumstances reviewed should generally include the following for each type of assessment.

   a. Held Orders: orders held by the electronic monitoring program will appear in ADC and require action, but not necessarily an assessment of the threshold limit. The following steps should generally occur to evaluate the held order and assist in determining if an assessment is warranted.

      a. Evaluate case within ADC, which appears on the dashboard.
      b. Identify customer by specifically reviewing the DEA #, name, location and class of trade.
      c. Determine the drug family for which the evaluation is generated by. This will be noted within ADC, indicated as Substance, on the Customer Cases tab of the Customer Details dashboard. Assess recent cases regarding the same drug family, or other drug families, to understand previous decisions and actions completed. This information can be found within ADC, indicated as Substance, on the Customer Cases tab of the Customer Details dashboard, as well. Opening a previous case and reviewing the Order Processing portion of the screen will outline the actions taken for that previously held order.
      d. If the customer's class of trade is Retail Chain, determine Cardinal Health's distribution position.[3] Analysis will vary depending on whether Cardinal Health is the customer's primary wholesaler or in some other distribution position.
      e. Review customer comments found within ADC on the QRA Info tab of the Customer Details dashboard. Use these comments to determine if any new information has been included since the prior review and, if so, determine the value of this new information in your analysis of the customer.
      f. Review any new or pertinent due diligence documents which are found within ADC on the Customer Profile Tab of the Customer Details dashboard. Any documents that have been added within the last year may be valuable to the analysis.
      g. Review the specifics of the held order to determine order size, accrual, and threshold. Accrual within ADC, indicated under Volume, on the Customer Cases tab of the Customer Details dashboard.
      h. Define Customer Zone within Tableau file, to determine the necessary requirements for customer analysis and threshold adjustments which can be found in Table 2: Customer Segmentation and Review Policies.[4]

   b. Early Dialogue:

      a. Review Early Dialogue within ADC to determine instances where communication may be necessary. Those Early Dialogue cases that are 75%-99% of accrual

[3] See Appendix 6 for Cardinal Health Distribution Position.
[4] See Appendix 2 for Customer Segmentation and Review Policies.

should be reviewed daily. To view cases within ADC, select Early Dialogue at the top of the Anti-Diversion Centralization – QRA Dashboard and filter to designated region by selected Region at the bottom of the screen.

b. Evaluate the instance within ADC to determine:
c. If the customer had been assessed within the last two (2) weeks regarding the specific drug family.
d. If new due diligence documents have been received or collected since the previous assessment. Be sure to compare the date listed in ADC with the date listed on the document to determine its relevance.
e. [redacted]
f. Determine if the instance warrants the creation of a manual case for threshold adjustment to be made. If a manual case is required for this customer, do this within ADC by selecting Create Case to the right of the Early Dialogue Events screen. Follow the process for Objective and Empirical review. Empirical review can be defined as a meaningful review that is based on judgment.

c. Proactive Communication:
   a. Evaluate information provided by customer or sales and determine if additional details regarding the situation are needed. If so, reach back out through sales to collect this information. If customer or sales provides only an account number or store number, you may utilize the Store Lookup database, which can be accessed on the I:drive by opening the Anti-Diversion Team Folder, then opening the Store Lookup folder, and entering the appropriate information.
   b. Create a manual case within ADC if sufficient information is provided by customer or sales by selecting Customer Search at the top of QRA Dashboard, typing in the customer's DEA #, displaying the customer record, selecting the Customer Cases tab of the Customer Details dashboard, and selecting Create Manual Case in the upper right corner. Follow the process for Objective and Empirical review. Instances where manual case creation is be necessary may include:
      i. The customer communicates that a pharmacy nearby is closing and it expects the need to increase its purchases by 15%. This 15% increase in purchases would cause threshold events, based on its current threshold for that drug family. The customer passes through objective criteria and empirical analysis.
      ii. The customer communicates that a recent theft has occurred and this has been confirmed through the documentation of a 106 – Theft Loss Report and a police report. Due to this confirmed theft, an increase for the month may be necessary.
      iii. The customer communicates that it will be or has started servicing new hospice or long-term care facilities, requiring a pharmacist's review of available information.

Upon review the set of circumstances for each type of assessment, a decision should be made as to whether or not the scenario warrants a review. An assessment is always required to increase a customer's threshold limit.

c. Assessment of the customer and its threshold is warranted in the following scenarios:

i. [redacted]

ii. [redacted]

iii. [redacted]

d. Assessment of the customer and its threshold is not warranted in the following scenarios[5] (No threshold adjustments are allowed):

i. Review of due diligence documents indicates that no new information or due diligence has been made available since the most previous review. Due diligence files will be listed in order from newest to oldest in the Customer-related Documents section on the Customer Profile tab of the Customer Details dashboard.

ii. [redacted]

iii. [redacted]

iv. The customer has been terminated from purchasing controlled substance products from Cardinal Health. This will be noted within ADC and can be found by opening the customer case and reviewing the threshold listed on the Order Processing section of the screen. A customer who has been terminated from purchasing controlled substances products from Cardinal Health will have a threshold of one (1). This will also be noted within ADC as Current Status on the Customer Block/Reinstate tab of the Customer Details dashboard.

[5] For held orders, this would result in the order being cut and reported as suspicious to the DEA.

4. **Objective Assessment:** When it is determined that a customer and a threshold limit warrant additional assessment, the customer's objective criteria should be assessed. The objective criteria include a standardized set of metrics used to assess the customer's overall profile. The review of objective criteria generally includes the following steps:

a. Review customer specific Tableau file, specifically evaluating the following components:
    a. Customer Zone of drug family or families triggering assessment.
    b. Review trend of drug family or families triggering assessment, specifically evaluating spikes and underlying strengths.
    c. [redacted]

        i. When a customer fails the objective criteria and, after empirical review, there is no justification for threshold adjustment:
            i. When appropriate, within the Customer Comments section of ADC, document the score, drug family and Customer Zone.
            ii. Within ADC, cut the order by selecting the Cut Order radio button found in the Order Processing section of the customer case screen.
            iii. Within ADC, adjust the accrual for the customer by selection the Adjust Accrual radio button found in the Order Processing section of the customer case screen.
            iv. Within ADC, report the order as suspicious by selecting the Report to DEA radio button found in the Order Processing section of the customer case screen.
            v. Communicate the decision and the reasoning to the appropriate sales personnel. Email templates for communication can be which can be accessed on the I:drive by opening the Anti-Diversion Team Folder, opening the Customer Communication Templates folder, and choosing the appropriate communication.
                a. For Retail Independent customers, the communication should be sent to the PBC responsible for the customer.

[6] See Appendix 3 for Objective Criteria and Score Model.

The sales rep can be identified within ADC on the Sales Rep tab of the Customer Details dashboard.

b. For Retail Chain customers, the communication should be sent to the primary Cardinal Health sales contact responsible for the National Account. A complete list of contacts for each National Account can be identified found in Table 4: National Accounts Contact List.[7]

vi. Customers may receive a specified percentage of dosage units over their thresholds, once an accrual per drug family. The percentage allotted [redacted] and can be found in Table 5: Customer Release Percentage.[8] If this release percentage is utilized during an accrual period, it should be noted, along with the drug family, within the Customer Comments section of ADC [redacted].

ii. When a customer passes the objective criteria:

i. When appropriate, within the Customer Comments section of ADC, document score, drug family and Customer Zone.

ii. Proceed to the empirical review in Step 5.

iii. For those customers with a threshold of 1, it is only necessary to note that the threshold is set at 1 or that the customer may not order from this drug family within the order processing and/or customer comments. However, if additional information is worth noting, it can be included.

5. **Empirical Assessment:** When it is determined that a customer passes the objective criteria, an empirical assessment of the customer and available information to assess the reasonableness of the information and underlying basis for the threshold limit increase. The review of empirical criteria generally includes the following steps:

a. Evaluate the order and historical order trend by reviewing customer's historical order pattern within the Tableau file to determine if the recent trend is reasonable and acceptable. [redacted]

I. [redacted]

II. [redacted]

III. [redacted]

[7] See Appendix 4 for National Accounts Contact List.
[8] See Appendix 5 for Customer Release Percentage.

b. Evaluate due diligence information by reviewing any information that has been made available within the last twelve (12) months. Review of any due diligence information outside of the twelve (12) month window is discretionary. As of right now, within ADC, the date associated with the document is the date on which it was loaded into Content Manager. Be sure to check the date the document was *created* in order to determine its relevance in the analysis process.
    a. If order pattern has significantly changed from historical order pattern and an unjustified or unreasonable spike is evident, communicate with sales team to collect necessary information to support the underlying change in ordering. Acceptable responses to support this type of change include:
        i. [redacted]
            i. [redacted]
                a. [redacted]
                b. [redacted]
            ii. [redacted]
    b. Historical trend for the drug family, which can be found within the Tableau file on the Drug Family tab at the bottom of the screen. This may also be found within ADC by selecting the appropriate drug family listed next to Qty Shipped This

[9] See Appendix 7 for Distribution Center Pharmacists Assignments.
[10] See Appendix 7 for Distribution Center Pharmacists Assignments.
[11] See Appendix 7 for Distribution Center Pharmacists Assignments.

Month (Dosage Units) found above the Order Processing section of the customer case screen. Situations where increased volume may be reasonable (non-exhaustive):

i. [redacted]
ii. [redacted]

c. [redacted]

d. Percentage of cash the customer accepts in regards to total prescriptions (controlled and non-controlled). [redacted] Ask the sales team to collect information regarding:
   i. What percentage of controlled prescriptions are paid for in cash?
   ii. What percentage of non-controlled prescriptions are paid for in cash?

[redacted]

e. On-site investigation reports
   i. When available, on-site investigation reports should be referenced. The review of the report should determine if red-flags were identified during the visit. Within the Investigation Final Report, specifically pay close attention to:
      a. Those questions with Yes/No answers highlighted in red and the accompanying explanations;
      b. Section 2. Dispensing Information, specifically noting total prescription count and percentage of cash information,
      c. Section 4. Know Your Customer, specifically noting the specialties serviced by the pharmacy [redacted]
      d. Section 5. Due Diligence, specifically noting the investigator's observations.
   ii. Full-site visit reports, conducted by an investigator, can be found within ADC or Content Manager under the naming convention 110 – Investigation Final Report.
   iii. Customer call survey, conducted by an investigator, can be found within ADC or Content Manager under the naming convention 062 – Customer Call Survey.
   iv. Surveillance site visits, conducted by an investigator, can be found within ADC or Content Manager under the naming convention 102 – Surveillance Visit.
   v. Sales site visit reports, conducted by a PBC, can be found within ADC or Content Manager under the naming convention 102 – Sales Site Visit.

f. Affiliations (prescriber specialties)

[redacted]

i. If available, this information will be noted in the customer's initial KYC or in new due diligence information collected since previous assessment. Within a 110 – Investigation Final Report or a 062 – Customer Call Survey, this information can be found in Section 4. Know Your Customer.

g. Upon receipt of information, if a pharmacist's opinion is needed, assign the case to the designated pharmacist, found in Table 7: Distribution Center Pharmacist Assignments.[13] To assign the case within ADC, select the "+" for the specific customer to drop down the specific case. Select Assign Case on far right and indicate the appropriate pharmacist whose review is requested. Pharmacist will then be responsible for reviewing the customer and proposing a threshold change, if warranted. [redacted]

h. [redacted]

6. Eligibility for threshold limit increase: If all objective and empirical criteria are satisfactory and a customer is eligible for threshold limit increase, the following steps should generally be completed to determine the appropriate limit to set the threshold limit. Instances outside of these general guidelines require approval at the Vice-President level or above.

a. Determine if a Sales Site Visit or QRA Site Visit it required by reviewing Table 2: Customer Segmentation and Review Responsibilities.[14] If a Sales Site Visit is required, it must have been completed within the last 90 days. If a QRA Site Visit is required, it must have been completed within the last 12 months.

i. If a Sales Site Visit has not been completed within the specified period of time, request a site visit within ADC by opening the customer case, checking the Site Visit box at the bottom of the Order Processing screen, and selecting Process. Selecting the Process button at the bottom of the screen, once all actions have been completed, will bring up a new screen allowing you to select Sales Site Visit. If the Sales Site Visit has not been completed within five (5) days, cut and report to the DEA as suspicious all held orders in the system and adjust the accrual. Review Sales Site Visit if completed within five (5) days. Subsequent orders will be held until the five (5) day limit has passed and then similar action will be taken on all held orders (i.e. move the threshold and release the orders, as appropriate, or cut all orders).

i. Any information received from the Sales, whether proactively or in response to an inquiry, should be documented on the 074 – KYC Justification Form appropriately and loaded into Content Manager.

[13] See Appendix 7 for Distribution Center Pharmacists Assignments.
[14] See Appendix 2 for Customer Segmentation and Review Policies.

ii. Communicate this message to sales through use of email templates, which can be accessed on the I:drive by opening the Anti-Diversion Team Folder, opening the Customer Communication Templates folder, and choosing the appropriate communication.

ii. If a QRA Site Visit has not been completed within the specified period of time, request a site visit within ADC by opening the customer case, checking the Site Visit box at the bottom of the Order Processing screen, and selecting Process. Selecting the Process button at the bottom of the screen, once all actions have been completed, will bring up a new screen allowing you to select QRA Site Visit and where the drug family of concern must be documented, as well. Document the QRA Site Visit request, within ADC, on the QRA Info tab of the Customer Details dashboard, specifying the drug family for which the review occurred. Until completion of the requested QRA site visit, all orders will be cut and reported to the DEA as suspicious and the accrual adjusted. The requestor of a QRA Site Visit will be notified through email when the document has been loaded within Content Manager.

i. Communicate this message to sales through use of email templates, which can be accessed on the I:drive by opening the Anti-Diversion Team Folder, opening the Customer Communication Templates folder, and choosing the appropriate communication.

iii. For Retail Chain customers, the requirements for Sales Site Visits and QRA Site Visits vary slightly from Retail Independent. For these customers, the review should be conducted as following:

i. Sales Site Visits

a. If the site visit request is for any drug family other than oxycodone and hydrocodone, the sales site visit does not have to be completed at the time of the threshold adjustment, but must be requested at the time the threshold adjustment is set or proposed.

b. If the site visit is for oxycodone or hydrocodone, the sales site visit must be completed prior to setting or proposing a threshold adjustment. Request the sales site visit within ADC and ensure its completion, prior to setting or proposing a threshold adjustment.

ii. QRA Site Visits

a. If a site visit is required by Table 2: Customer Segmentation and Review Responsibilities[15], this must be completed prior to setting or proposing a threshold adjustment.

b. Determine authority to set threshold by reviewing Table 2: Customer Segmentation and Review Responsibilities.[16] ADC will automatically trigger 2-person reviews in the system, when required.

[15] See Appendix 2 for Customer Segmentation and Review Policies.
[16] See Appendix 2 for Customer Segmentation and Review Policies.

b. If the all requirements are completed, set or propose threshold limit within ADC by selecting the Adjust Threshold radio button found in the Order Processing section of the customer case screen. Selecting the Process button at the bottom of the screen, once all actions have been completed, will bring up a new screen allowing you to set or propose the new threshold limit. Set or propose threshold limit based on the Threshold Change Reference found in the Tableau file. The threshold limit should be set no higher than the Threshold Change Reference suggests, but may be set lower should it be reasonable to do so.
   a. Threshold limits are aligned to the prescription volume of a customer.
   b. [redacted]
   c. [redacted]
   d. The Threshold Change Reference found in the Tableau file takes into account total prescription volume.
   e. Account for AAP

7. [redacted]

8. **Theft**

In the event that a PBC or customer reports a theft of controlled substances, confirm the receipt of 106 form or police report, which indicates exactly what products were lost in the theft, and adjust thresholds accordingly to allow for the reorder of these items. In these instances, the site visit and LV-TAC approval needs outlined in Table 2: Customer Segmentation and Review Responsibilities, are not required. Be sure to adjust threshold back down to prior level upon the specific accrual reset date for the customer. Attach information to a completed 074 form and load into Content Manager.

9. **Secondary Threshold Limits**

Secondary thresholds for Retail Chains will remain static and no changes will be made to the previously set limits. For a list of secondary thresholds reference Table 8: Secondary Customer Threshold Limits.[17]

10. [redacted]

[17] See Appendix 8 for Secondary Customer Threshold Limits.

[redacted]

11. [redacted]

12. **Threshold Adjustments to Non-Top 13 Drug Families**
For those drug families outside of the non-top 13 drug families, apply the logic outlined in Table 9: Non-Top 13 Drug Family Threshold Change Guidance.[18]

13. **CVS/Walgreen/Kroger – Oxycodone – Zone A**
Prior to making any adjustments for Oxycodone Zone A CVS, Walgreen, or Kroger stores, where there is a compelling reason for adjustment to the oxycodone threshold, contact Sales to determine the number of hydrocodone dosage units supplied by the chain warehouse. Incorporate this information into the review to determine whether an adjustment is warranted.

[18] See Appendix 9 for Non-Top 13 Drug Family Threshold Change Guidance.

APPENDIX

Appendix 1

Table 1: List of 13 Drug Families

Base Code	Description
	[redacted]

Appendix 2

Table 2: Customer Segmentation and Review Responsibilities

Zone	Authority to Set Limit			Information Needed			
	Customer Analytics	2-Person Review	LV-TAC	Sales SV	QRA SV	Objective Criteria	Subjective Criteria
[redacted]							

*** Pharmacists determine whether a QRA site visit is needed.**
**** Sales Site Visits to be requested at time of threshold adjustment (Retail Independent and Retail Chain).**

Appendix 3

Table 3: Objective Criteria & Score Model

Criteria	Percent Within	Floor Dosage Units	Percentage		Score Reference			
			Floor	Cap	3	4	5	12
[redacted]								

***Only criteria one through three (1-3) apply to CVS, Kroger, and Walgreens.**

Appendix 4

Table 4: National Accounts Contact List

Customer Name	National Markets Sales
Balls Food Group	Brandon Wilkins/Bob Balcerek/Chris Wendel
Bashas	Yvonne Foster/Chris Wendel
BiLo	Alan Pinyerd/Chad Schwinn/Susan Hoffman/Andy Grant
Buehler's/Ritzman	Brandon Wilkins/Bob Balcerek/Chris Wendel
C&K Markets	Ryan McCoy/Chris Wendel
CVS	Alana Millonzi/Mollie Turner/Greg Ewing
Discount Drug Mart	Brandon Wilkins/Bob Balcerek/Andy Grant
DZA/Hannaford/Food Lion/Harveys/Sweetbay	Brandon Wilkins/Bob Balcerek/Andy Grant
Fruth	Jennifer Carley/Susan Hoffman/Chris Wendel
Harris Teeter	Erin Wright/Chad Schwinn/Susan Hoffman/Andy Grant

Hi School	Ryan McCoy/Bob Balcerek/Chris Wendel
Kerr	Suzanne Livingston/Chad Schwinn/Susan Hoffman/Andy Grant
Kmart	Alan Pinyerd/Mollie Turner/Greg Ewing
Kroger	Erin Wright/Lisa Penn
Lewis Drug	Brandon Wilkins/Bob Balcerek/Chris Wendel
Pharmaca	Ryan McCoy/Yvonne Foster/Bob Balcerek/Chris Wendel
Rosauers	Ryan McCoy/Bob Balcerek/Chris Wendel
Safeway	Jennifer Carley/Bob Balcerek/Andy Grant
Walgreens/ Duane Reade	Erin Wright/Lisa Penn/Kraig Corwin

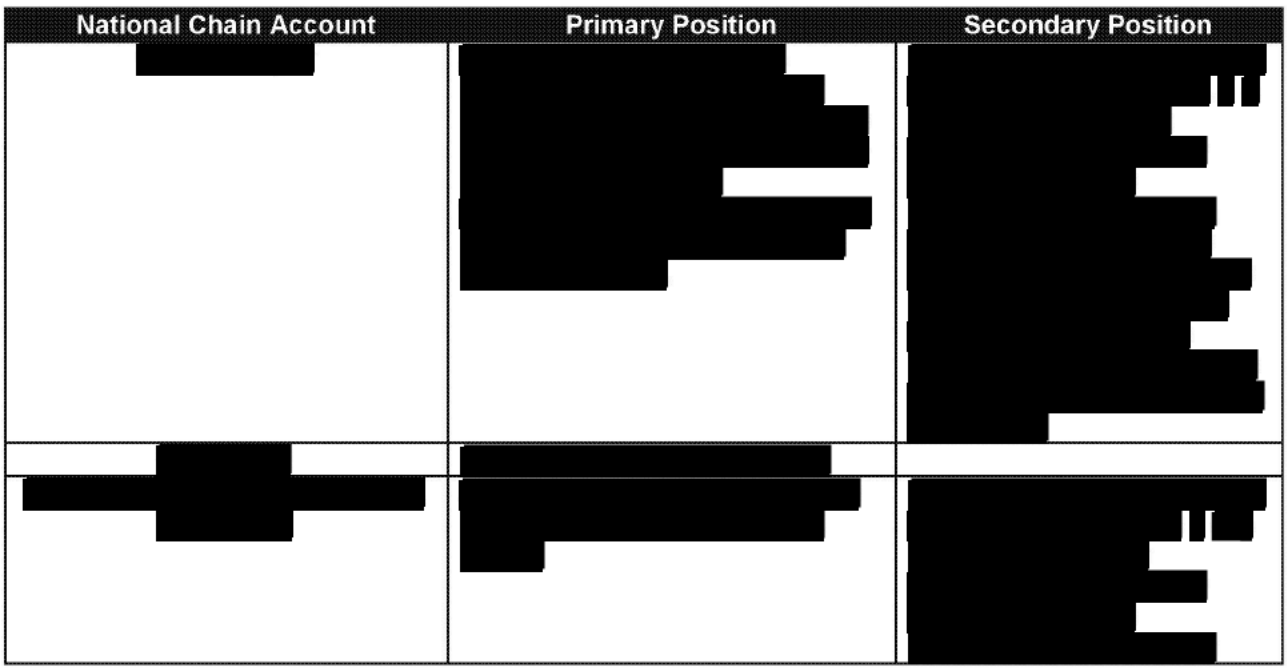
Appendix 5

Table 5: Customer Release Percentage

Threshold Limit	Allowable Percentage Over Threshold per Drug Family per Accrual Period	Example
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Appendix 6

Table 6: Cardinal Health Distribution Position



Appendix 7

Table 7: Distribution Center Pharmacists Assignments

Distribution Center	DC#	Accrual Cycle End Date
Pharmacist – Janet Ng		

Pharmacist – Kimberly Anna-Soisson		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
Pharmacist- Doug Emma		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
Pharmacist – William Brady		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
Pharmacist – Christopher Forst		
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]		[redacted]

Appendix 8

Table 8: Secondary Customer Threshold Limits

Base Code	Description	Limit
[redacted]		

Appendix 9

Table 9: Non-Top 13 Drug Family Threshold Change Guidance

Category	Authority to Set Limit Daunt's Team	2-Person Review (Pharmacist)	2-Person Review (NP)
[redacted]			